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EXAMINER

SRIVASTAVA, KAILASH C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1651

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/974,749

Applicant(s)

YUAN, CHUN-SU

Examiner

Dr. Kailash C. Srivastava

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7, 10-22, 30, 33-35, 38 and 51-74 is/are pending in the application.
- 4a) Of the above claim(s) 15-16 and 54-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7, 10-14, 17-22, 30, 33-35, 38 and 51-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>07/25/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's response filed November 03, 2003, to Office Action mailed April 09, 2003 is acknowledged and entered. Text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.
2. Claims 5-6, 8-9, 31-32 and 36-37 are cancelled.
3. Claims 1, 3-4, 10, 30 and 33-35 are amended.
4. Claims 52-74 are added.
5. Claims 1-4, 7, 10-14, 17-22, 30, 33-35, 38 and 51-74 are pending.
6. Newly submitted claims 53-74 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 54-74 recite subject matter drawn to non-elected Claim 24 (See Office Action mailed November 22, 2002 and applicant's response to said Office action filed on 12/27/2002).

Since applicants have received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 54-74 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Examiner suggests that to expedite prosecution, the non-elected claims cited *supra* (i.e., Claims 54-74) be canceled in response to this Office action.

7. Claims 1-4, 7, 10-14, 17-22, 30, 33-35, 38 and 51-53 are examined on merits.

Information Disclosure Statement

8. Applicant's Supplemental Information Disclosure (i.e., IDS) filed 07/01/2003 fails to comply with 37 CFR 1.98(a)(3) because this IDS was filed after the first Office Action on Merits and therefore, requires a fee that has not been paid in accordance with **37 CFR 1.98(a)(3)**. It has been placed in the application file, but the information referred to therein has not been considered.
9. Applicant's Supplemental Information Disclosure (i.e., IDS) filed July 25, 2003 has been made of record and considered.

Claim Rejections - 35 U.S.C. § 112

10. Claims 1-4, 7, 10-14, 17-22, 30, 33-35, 38 and 51 and newly drafted Claims 52-53 remain rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Phrases "active compound" and "wherein the active compound comprises ginsenoside Re"/ "purified ginsenoside Re" in Claims 1, 3, 4, 30 and 34 are vague, unclear and confusing because how can a compound comprise another compound? A composition, however, can comprise a compound. Appropriate correction is required.
- Phrase "an ant-hyperglycemic compound" in Claims 3, and 35 is vague, unclear and confusing because metes and bounds for said phrase are not clearly defined Does the term mean a compound that lowers hyperglycemia or does it eliminate hyperglycemia? Applicant should clearly define the phrase ant-hyperglycemic compound".
- Phrase "an anti-obesity compound" in Claims 10, 33 and 38 is unclear and confusing because metes and bounds for said phrase are not clearly defined. Does the phrase "an anti-obesity compound" mean a compound that lowers obesity or does it eliminate obesity? Applicant should clearly define the phrase ant-obesity compound".
- While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947. The phrase "anti-hyperglycemic compound" in claims 3, and 35 is not an art accepted phrase/ term (See Stedman's Medical Dictionary). The examiner suggests that the applicant replace the phrase "anti-hyperglycemic compound" with a phrase/term that is art-accepted.
- While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947. The phrase "anti-obesity compound" in claims 3, and 35 is not an art accepted phrase/ term (See Stedman's Medical Dictionary). The examiner suggests that the applicant replace the phrase "anti-obesity compound" with a phrase/term that is art-accepted.

All other claims depend directly from the rejected claims and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

In response to the rejections made to Claims 3, 10, 33, 35 and 38 under 35 U.S.C. §112, second paragraph in Office Action mailed April 9, 2003, applicant argues that in view of the amendments made to said claims "the rejection is now believed to be moot". Applicant's arguments filed November 03, 2003 have been fully considered but they are not persuasive. The rejection under 35 U.S.C. § 112, second paragraph is adhered to for the reasons of record and the additional reasons discussed above.

Claim Rejections Under 35 U.S.C. § 102(b)/ § 103(a)

11. Claims 1-4, 7, 10-14, 17-22, 30, 33-35, 38 and 51 stand rejected under 35 U.S.C. §102(b) as anticipated by JP 07267977A (English Abstract), with evidence provided by Gruenwald, J. et al. (eds.), (PDR for Herbal Medicines. 1998. Medical Economics company, Montvale, N.J., Pg. 1009).

Claims 1-4, 7, 10-14, 17-22, 30, 33-35, 38 and 51 stand rejected under 35 U.S.C. § 103 (a) as obvious over JP 07267977A (English Abstract) with support from Mathur et al. (U.S. Patent 6,326, 202) and Coombs (Dictionary of Biotechnology, 1986 Elsevier Scientific Publishing Co., Inc., Page 46) in view of Yegorova et al. (U. S. Patent 6,399,089)

Applicant argues that amended claims specify the specific compound to be ginsenoside Re and therefore, the Examiner-cited references neither expressly or inherently teach or suggest the instantly claimed invention- that of treating diabetes, hyperglycemia or for decreasing obesity or blood glucose with the administration of ginsenoside Re. Citing a number of case laws, applicant further argues that "Only evidence in support of alleged inherency is the mention of ginseng extracts in JP 07267977 A and a description in Gruenwald et al. of a laundry list of components obtained in *Panax ginseng*". Applicant further argues that Gruenwald et al. reference is silent about the presence of said compounds in extract from ginseng berry.

Teachings from Abstract of JP 07267977A with evidence provided from Gruenwald et al. still inherently anticipate the invention claimed in presently drafted Claims 2, 7, 11-14, 17-22, 51, newly presented Claims 52-53 and presently drafted amended Claims 1, 3-4, 10, 30 and 33-35 for the reasons of record at Page 4, Lines 3 to 20 in the office Action mailed April 9, 2003.

Feit et al. (2003, J. Pat. Trade. Off. Soc., Vol. 85, No. 1, pages 5-21) teach three criteria for inherency. (1) The most important criterion is certainty. Citing *In re Tomlinson* and *In re Zierden*, Feit et al. state that certainty is established when the reference process necessarily results in the claimed process as opposed to a possibility. (2) The second criterion is chronology; it will always happen. Feit et al. state that the chronological test is forward chronology. Citing *Eli Lilly and Co. v Barr Laboratories, Inc.*, Feit et al. argue that the claimed result must always be obtained based upon the prior art method. 3) The third criterion is the legal standard. Feit et al., citing *Continental Can*, state that the legal standard is whether the missing descriptive material would be so recognized by a person of ordinary skill in the art as necessarily present in the thing.

Teachings from Abstract of JP 07267977A with evidence provided by Gruenwald et al., Mathur et al. (U.S. Patent 6,326,202) and Coombs (Dictionary of Biotechnology, 1986 Elsevier Scientific Publishing

Co., Inc., Page 46) in view of Yegorova et al. (U. S. Patent 6,399,089) renders the instantly claimed invention obvious for the reasons of record at Page 5, Line 8 to Page 6, Line 22 in the office Action mailed April 9, 2003. Furthermore, the ginseng extract, unless demonstrated to the contrary, will be comprised essentially of same components regardless of the plant part (root or fruit) from where the extract is obtained because ginseng callus produces ginsenoside Re (see Mathur et al., Table 3,) and it is well established that the callus is an undifferentiated artificial culture of plant tissue (See Coombs, Dictionary of Biotechnology, 1986 Elsevier Scientific Publishing Co., Inc., Page 46, Column 1, Lines 41-46).

Thus, in absence of any evidence to the contrary, applicants' claimed invention is anticipated by, and is obvious over examiner-cited references.

In response to applicant's arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicants' argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, those reasons are cited at pages 3-5 of the Office Action mailed April 23, 2003 as paper number 9. Furthermore, a rejection under 35 U.S.C. § 103 (a) based upon the combination of references is not deficient solely because the references are combined based upon a reason or technical consideration which is different from that which resulted in the claimed invention (*Ex parte Raychem Corp.*, 17 U.S.P.Q. 2d 1417).

Applicant's arguments filed November 03, 2003 have been fully considered but they are not persuasive. The rejection under 35 U.S.C. § 102(b)/ § 103(a) is adhered to for the reasons of record and the additional reasons discussed above.

CONCLUSION

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. No Claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (571) 272-0926 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1651
(571) 272-0923

February 9, 2004



CHRISTOPHER R. TATE
PRIMARY EXAMINER